



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,121	03/26/2004	Kevin D. Burrow	7432-0054	9223

7590 03/17/2006

E. Victor Indiano
Suite 850
One North Pennsylvania Street
Indianapolis, IN 46204

EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
----------	--------------

3743

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,121	BURROW ET AL.	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claims 6, 11 and 14, "...no more than about 5 cm of water..." the specification provides support in paragraph [00123] for "...no more than 5 cm of water..." not the limitation of "...no more than **about 5 cm** of water...". With respect to claims 7-14, the ratio of the outer tube diameter of the inspiratory tube to the inner diameter of the expiratory tube in the specification is actually the ratio of the mean outer tube diameter of the inspiratory tube to the mean inner diameter of the expiratory tube, note paragraphs [00125] and [00126].

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the claims are directed to first leg, second legs and first and second angles, it is unclear if the claims are suppose to be directed to how the tubes are manufactured, as the first and second legs along with the first and second angles are outlined in the specification directed the method of how the tubes are made. Therefore it is unclear as to what is being claimed as support for the legs and angles based on the originally filed specification appears to be directed to the how the tubes are manufactured (note paragraphs [0111]-[0117]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clawson (WO 85/05277) in view of Leagre (5,404,873) and Rosenkoetter et.al. (5,894,839) .

Clawson in a unilimb breathing circuit discloses a proximal end coupling member (Fig. 4), a distal end coupling member (Fig. 4), a pleated expiratory tube (110) having a first end coupled to the proximal end coupling member, and a second end coupled to the distal end coupling member, the expiratory tube being expandable between a fully

compressed rest position and a fully expanded rest position, and having a plurality of intermediate rest positions wherein the expiratory tube is capable of maintaining its rest length without the exertion of an external force (Page 5), and a pleated inspiratory tube (108) having a first end coupled to the proximal coupling member (Fig. 4), and a second end coupled to the distal end coupling member (Fig. 4), the inspiratory tube being expandable between a fully compressed position and a fully expanded position, and having a plurality of intermediate rest positions wherein the inspiratory tube is capable of maintaining its rest length without the exertion of an external force (Page 5), wherein the length of the inspiratory tube is greater than the length of the expiratory tube (based on how the inspiratory is expanded it is greater in length than the expiratory tube; Fig. 4).

With respect to the length of the inspiratory tube being greater than the length of the expiratory tube. Leagre teaches the length of the inspiratory tube greater than the length of the expiratory tube (Col. 7, lines 10-31). Also, Rosenkoetter in a unilimb tubing system teaches the lengths of the tubes may be any standard or selected tubing length such as those typically used for anesthesia or respiratory breathing circuits (Col. 2, lines 7-13). Based on the teachings of Leagre and Rosenloetter, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the length of the inspiratory tube greater than the length of the expiratory tube as such is known in the art.

The difference between Clawson and claim 2 is the length of the inspiratory tube being greater than the length of the expiratory tube by between about 1 and 7 inches

when each of the inspiratory and expiratory tubes are in there fully expanded positions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the length of the inspiratory tube between about 1 and 7 inches, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With respect to claim 3, note rejection of claim 2 above.

With respect to claim 12, Clawson discloses a proximal end coupling member (Fig. 4) a distal end coupling member (Fig. 4), a pleated outer tube having a first end coupled to the proximal end coupling member (110), and a second end coupled to the distal end coupling member, the outer tube including a series of pleats having a first leg and a second leg (Figs. 2-5, 11, 12), the first legs being joined to define a series of peak points (Figs. 2-5, 11, 12), the outer tube pleats being expandable between a fully compressed rest position and a fully expanded rest position, and having a plurality of intermediate rest positions wherein the outer tube is capable of maintaining its rest length without the exertion of an external force (Figs. 2-5, 11, 12), the first and second legs of the outer pleats being disposed at a first angle when in the compressed rest position, and at a second angle when in the expanded rest position (Figs. 2-5, 11, 12); and a pleated inner tube (108) having a first end coupled to the proximal coupling member, and a second end coupled to the distal end coupling member, the inner tube including a series of pleats having a first leg and a second leg (Figs. 2-5, 11, 12), the first legs being joined to define a series of peak points (Figs. 2-5, 11, 12), the inner tube

pleats being expandable between a fully compressed rest position and a fully expanded rest position, and having a plurality of intermediate rest positions wherein the inner tube is capable of maintaining its rest length without the exertion of an external force (Figs. 2-5, 11, 12), the first and second legs of the inner pleats being disposed at a first angle when in the compressed rest position, and at a second angle when in the expanded rest position (Figs. 2-5, 11, 12), wherein the second angle of the inner tube pleats is greater than the second angle of the outer tube pleats. It would have been obvious to one of ordinary skill in the art that the second angle of the inner pleats is greater than the second angle of the outer tube pleats because the inner tube is longer than the outer tube (as well known that the inner tube can be longer than the outer tube as taught by Leagre and Rosenloetter, note rejection of claim 1 above) and based on applicant's specification [0116]"... These differences in angle.... and differ largely due to the differences in size between the inspiratory tube and expiratory tube".

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clawson et.al. (WO 85/05277)/Leagre (5,404,873)/Rosenkoetter et.al. (5,894,839) as applied to claim 1 above, and further in view of Nowacki et.al. (4,621,634).

The difference between Clawson and claim 4 is the distal end coupling member having axis of the terminus being radially offset from the axis of the distal end coupling member. Nowacki in a connector discloses a connector with an axis of the terminus being radially offset from the axis of the distal end coupling providing a crank effect facilitating assembly of the tapered exhaust fitting, thereby assuring a tighter connection

(Abstract; Col. 1, lines 50-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the coupling of Clawson with any well known coupling with a axis of a terminus being radially offset doing so would have provided a coupling with a crank effect facilitating assembly of the tapered exhaust fitting, thereby assuring a tighter connection including the coupling taught by Nowacki.

With respect to claim 17, note rejection of claim 4 above.

Claims 5-11, 13-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clawson (WO 85/05277)/ Leagre (5,404,873)/ Rosenkoetter et.al. (5,894,839) as applied to claim 1 above, and further in view of Fukunaga (4,265,235).

With respect to claim 5, Clawson discloses a unilimb breathing circuit comprising: a proximal end coupling member (Fig. 4), a distal end coupling member (Fig. 4), a pleated expiratory tube (110) having a first end coupled to the proximal end coupling member (Fig. 4), a second end coupled to the distal end coupling member (Fig. 4), an inner diameter and an outer diameter, the expiratory tube being expandable between a fully compressed rest position and a fully expanded rest position (Page 5), and having a plurality of intermediate rest positions wherein the expiratory tube is capable of maintaining its rest length without the exertion of an external force (based on the corrugated tubing, Page 5), and a pleated inspiratory tube (108) having a first end coupled to the proximal end coupling member (Fig. 4), a second end coupled to the distal end coupling member (Fig. 4), an inner diameter and an outer diameter (Fig. 4), the inspiratory tube being expandable between a fully compressed position and a fully

expanded position (based on the corrugated tubing, Page 5), and having a plurality of intermediate rest positions wherein the inspiratory tube is capable of maintaining its rest length without the exertion of an external force (based on the corrugated tubing, Page 5), With respect to the limitations of, wherein the ratio of the outer diameter of the inspiratory tube to the inner diameter of the expiratory tube is sized to minimize flow resistance there between, while facilitating generally linear compressibility and expandability of the inspiratory and expiratory tube, Fukunaga in a unilimb tube teaches the difference in the diameters of the two tubes (i.e., inspiratory/expiratory) is such that a sufficient volume of expiratory gases may pass between the outer wall of the inner tube and the inner wall of the outer tube (Col. 6, lines 5-12). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the ratio of the outer diameter of the inspiratory tube to the inner diameter of the expiratory tube sized to minimize flow resistance there between, while facilitating generally linear compressibility and expandability of the inspiratory and expiratory tube, because such is known in the art as taught by Fukunaga.

With respect to claims 6-10, note rejection of claim 2 above.

With respect to claim 11, and the flow resistance of the breathing circuit being such that at 60 liters/minute of flow the pressure drop across the circuit is no more than about 5 cm of water, based upon the teachings of the diameter size of Fukunaga such would be inherently known. As for the specific diameter ranges, note claim 2 above.

With respect to claim 13, note rejection of claim 5 above.

With respect to claims 14-16, 18, and 19, note rejections of claims 1 and 2 above.

Response to Arguments

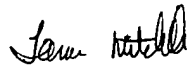
Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Clawson discloses little about how to construct such a co-axial respiratory circuit containing pleated tubes, which may be correct. However, the claims are not directed to a process of manufacturing the co-axial tubes, therefore, the end product, which is the tubing is what determines the patentability (Note MPEP 2100). Clawson has all the structural limitations of applicant's tubing and the process of how the tubing is manufactured does not matter, it is the end product (i.e., the tubing). As to the Nowacki reference, while applicant may have different reasoning for the radially offset distal terminus Nowacki does teach such terminus and therefore one of ordinary skill in the art would look to Nowacki for use of a connector which terminus is radially offset (note rejection above).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Primary Examiner
Art Unit 3743
March 8, 2006


TKM